UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/872,526	06/01/2001	Peter M. Bonutti	BON-1360-7	3309

33771 7590 06/16/2011

PAUL D. BIANCO
Fleit Gibbons Gutman Bongini & Bianco PL
21355 EAST DIXIE HIGHWAY
SUITE 115
MIAMI, FL 33180

EXAMINER	
RAMANA, ANURADHA	
ART UNIT	PAPER NUMBER
3775	

MAIL DATE	DELIVERY MODE
06/16/2011	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/872,526	BONUTTI, PETER M.	
	Examiner	Art Unit	
	Anu Ramana	3775	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 February 2011*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *36,38-43,46-50,53,57,59-61 and 66-111* is/are pending in the application.

4a) Of the above claim(s) *68-79,86 and 87* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36,38-43,46-50,53,57,67,82-85,88-91,93, and 95-111* is/are rejected.

7)☒ Claim(s) *59-61,66,80,81,92 and 94* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

In view of the Arguments presented in the Appeal Brief submitted on, February 2, 2011, PROSECUTION IS HEREBY REOPENED. To avoid abandonment of the application, appellant must exercise one of the following two options:

(1) file a reply under 37 CFR 1.111; or,

(2) initiate a new appeal by filing a notice of appeal under 37 CFR 41.31 followed by an appeal brief under 37 CFR 41.37. The previously paid notice of appeal fee and appeal brief fee can be applied to the new appeal. If, however, the appeal fees set forth in 37 CFR 41.20 have been increased since they were previously paid, then appellant must pay the difference between the increased fees and the amount previously paid.

A Supervisory Patent Examiner (SPE) has approved of reopening prosecution by signing below:

/Thomas C. Barrett/
Supervisory Patent Examiner, Art Unit 3775

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 36, 53, 82, 84, 85, 95, 101-104, 107, 108, 110 and 111 are rejected under 35 U.S.C. 103(a) as being unpatentable over "Transabdominal Fine Needle Biopsy from Chorionic Villi in the First Trimester, Steen Smidt-Jensen and Niels Hahnemann, Prenatal Diagnosis, Vol. 4, 163-169 (1984) (or Steen et al. hereafter)" in view of, "Fetal

Tissue Transplants," John A. Robertson, Washington University Law Quarterly (Vol. 66, No. 3, 1988).

Steen et al. disclose a technique for obtaining fetal tissue by percutaneous insertion of a 1-2 mm guide needle or cannula with aspiration or suction of fetal tissue using a syringe attached to a 0.7 mm needle or trocar or instrument under ultrasonic control. Steen et al. also disclose that the obtained fetal tissue is used for culturing (see "Summary," pp. 164 and 165).

Steen et al. is silent about implanting the extracted fetal tissue in a patient.

It is well known to use fetal tissue to cure sick patients, for e.g., patients suffering from central nervous system disorders, diabetes etc. (Washington Law Quarterly).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized the cell lines obtained by culturing fetal tissue extracted by the method of Steen et al. for reimplantation in a patient since it was known in the art to use fetal tissue for treatment of various diseases.

Regarding claims 82 and 95, it is the Examiner's position that 0.7 mm needle used in the Steen et al. procedure is flexible.

Claims 40-42 and 88 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steen et al. and Robertson, as applied to claim 36, further in view of "Fetal Tissue Sampling - The San Francisco Experience with 190 pregnancies," Golbus MS, McGonigle KF, Goldberg JD, et al. (or Golbus et al. hereafter)," West J Med 1989 Apr; 150: 423-430).

The combination of Steen et al. and Robertson disclose all elements of the claimed invention except for the steps of irrigating fetal tissue.

It is well known to flush samples of fetal tissue from a needle with saline solution for further processing wherein the fetal tissue is extracted by suction using a syringe. For e.g., see Golbus et al. wherein the fetal tissue is flushed from the needle with 0.9% saline solution (pages 423-424). It is the Examiner's position that the claimed method steps, of alternating irrigation and suction, are rendered obvious by the number of

aspirations performed to extract a required amount of fetal tissue. Thus, several aspirations would involve alternating suction and irrigation.

Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have utilized flushing or irrigation with saline solution, as taught by Golbus et al., in the method of the combination of Steen et al. and Robertson, to remove fetal tissue from the needle used for extraction.

Claims 43 and 89 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steen et al. and Robertson, as applied to claims 36 and 84, further in view of Molomut et al. (US 3,224,434).

The combination of Steen et al. and Robertson discloses all elements of the claimed invention except for the use of a syringe with a built-in filter for collection of tissue fragments or cells.

Molomut et al. teach the use of a syringe with a built-in filter such that when suction is applied to collect tissue fragments or cells, the filter traps the cells for subsequent analysis (col. 2, lines 25-72 and col. 3, lines 1-39).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of a syringe with a built-in filter, as taught by Molomut et al., to the method of the combination of Steen et al. and Robertson, would have yielded predictable results, i.e., enhanced collection of cells for subsequent processing steps.

The method steps of claims 43 and 89 are rendered obvious by the above discussion.

Claims 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Steen et al. and Robertson, as applied to claims 36 and 84, further in view of Gill et al. (US 4899729).

The combination of Steen et al. and Robertson discloses all elements of the claimed invention except for an expansible cannula.

Gill et al. teach an expansible cannula for minimizing damage to tissue when used to form and maintain a hole in tissue (col. 3, lines 40-45 and col. 4, lines 9-29).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of a expansible cannula to the method of the combination of Steen et al. and Robertson, would have yielded predictable results, i.e., access with minimal damage to surrounding tissues.

Claims 36, 38-40, 46-50, 53, 67, 84-85, 88, 90-91, 93, 95, 96, 99, 100-106, and 109-111 are rejected under 35 U.S.C. 103(a) as being unpatentable over, Rudall K.M., Wickham, G. A., “Development of wool follicles and fibers on autoplastic grafts of stored foetal lamb skin,” pp. 75-88 of book titled "Biology of the skin and hair growth," Americal Elsevier Publishing Company, Inc., 1965 (hereafter Rudall et al.) in view of Lars Lofberg and Bjorn Gustavii (or Lofberg et al. herein), “Blind” versus direct vision technique for fetal skin sampling in cases of prenatal diagnosis,” Clinical Genetics, 1984, Vol. 35, pages 37-41.

Rudall et al. disclose the method steps of: obtaining fetal tissue from the donor or fetus; irrigating or immersing the tissue in glycerol; maintaining sterility and viability of the excised tissue; treating the graft with a material such as serum or a biodegradable material or polymer or adhesive element or fibrin or “tissue grafts”; and implanting the graft material in a patient, i.e., the delivered lambs (pages 76-78).

Rudall et al. disclose all elements of the claimed invention except for: (1) obtaining the skin samples by a percutaneously inserted cannula; and (2) a cutting or removal device to excise tissue utilizing suction and irrigation to move tissue along a passage of the device.

Lofberg et al. teach in utero skin sampling using a two-cannula biopsy technique wherein a trocar and cannula are introduced into the amniotic cavity, followed by removal of the trocar and insertion of a needlescope. A biopsy forceps is then inserted through the cannula to obtain a skin sample under direct vision (pages 39-40).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of obtaining skin

samples in utero, as taught by Lofberg et al., in the Rudall method would have yielded predictable results, i.e., skin sampling while minimizing trauma to the mother.

Regarding claims 38 and 39, it is noted that these steps are obvious steps while using an instrument such as a biopsy forceps for cutting tissue.

Claims 57, 82-83, 95 and 96 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudall et al. and Lofberg et al., as applied to claims 36 and 84, further in view of Romaniuk et al. (US 4785825).

The combination of Rudall et al. and Lofberg et al. disclose all elements of the claimed invention except for the specific structure of the biopsy forceps.

Romaniuk et al. disclose a safety biopsy forceps with a flexible shaft, a pulling wire or drive means 2 that is disposed within the outer member of the shaft and moves the cutting or grasping element 4. The Romaniuk et al. biopsy forceps has separable elements making the forceps easy to manufacture and clean or sterilize. Further, the opening angles of the cutting elements can be adjusted by attaching cutting elements according to specific conditions at the cutting site (Figs. 1-2, cols. 1-3).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of obtaining a tissue sample using a safety biopsy forceps, as taught by Romaniuk et al., in the method of the combination of Rudall et al. and Lofberg et al. would have yielded predictable results, i.e., ease of adjustment of the opening angles of the forceps and ease of cleaning.

Regarding claims 83 and 96, it is noted that due to a flexible shaft, the Romaniuk biopsy forceps is movable or capable of being moved along a nonlinear path.

Claims 97 and 98 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rudall et al. and Lofberg et al., as applied to claims 36 and 84, further in view of Gill et al. (US 4899729).

The combination of Steen et al. and Robertson discloses all elements of the claimed invention except for an expansible cannula.

Gill et al. teach an expansible cannula for minimizing damage to the tissue in order to form and maintain a hole in tissue (col. 3, lines 40-45 and col. 4, lines 9-29).

Therefore, it would have been recognized by one of ordinary skill in the art at the time the invention was made that applying the known technique of a expansible cannula to the method of the combination of Rudall et al. and Lofberg et al., would have yielded predictable results, i.e., forming an access pathway with minimal damage to surrounding tissue.

Response to Arguments

Applicant's arguments filed in the Appeal Brief dated 02/02/2011 have been fully considered.

Upon further consideration, the Examiner has withdrawn the rejections under 35 USC 112 first paragraph with respect to "maintaining viability" mainly because the extracted tissue must have some viable cells if it is to be used for transplanting.

Applicant's arguments with respect to the rejection of claims 101-108, 110 and 111 under 35 USC 112 first paragraph are persuasive. Accordingly, the rejection has been withdrawn by the Examiner.

Applicant's arguments with respect to the rejection of claims 110 and 111 under 35 USC 112 second paragraph are persuasive, accordingly, the rejection has been withdrawn by the Examiner.

Upon further consideration of Applicant's arguments with respect to the limitation "percutaneously through a cannula", new rejections have been made in this office action.

Allowable Subject Matter

Claims 59-61, 66, 80, 81, 92 and 94 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anu Ramana whose telephone number is (571)272-4718. The examiner can normally be reached Monday through Friday between 8:00 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Barrett can be reached at (571) 272-4746. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AR
June 7, 2011

/Anu Ramana/
Primary Examiner, Art Unit 3775